REMARKS

The Office Action dated November 15, 2004, has been received and reviewed.

Claims 1-22 are currently pending an under consideration in the above-referenced application. Of these, claims 1-16 and 18-22 stand rejected, while it has been indicated that claim 17 is drawn to subject matter which is "free of the prior art."

Reconsideration of the above-referenced application is respectfully requested.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 22 stand rejected under 35 U.S.C. § 112, second paragraph, for purportedly being indefinite. Specifically, claim 22 has been rejected on the basis that "[i]t is not clear how or what aspect of the 'strength' of the immune system can be measured." Office Action, page 2.

It is respectfully submitted that the strength of an immune system can be measured by its response to certain stimuli. In this case, the strengthening of an immune system is identified by swelling of mouse footpads, which indicates and increased response of immune cells (T-cells) to the site of a pathogen due to stimulation by transfer factor.

Accordingly, it is respectfully submitted that one of ordinary skill in the art would recognize the meaning of the phrase "strengthen an immune system," as used in claim 22. Therefore, it is respectfully requested that the 35 U.S.C. § 112, second paragraph, rejection of claim 22 be withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 1-3, 7-16, and 18-22 stand rejected under 35 U.S.C. § 102(b) for reciting subject matter which is purportedly anticipated by that described in U.S. Patent 5,080,895 to Tokoro (hereinafter "Tokoro").

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Express descriptions are those that are readily apparent from the disclosure of a reference.

M.P.E.P. § 2112 provides guidelines on whether or not a claim element has been inherently described by a reference:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic. *In re Rijckaert,* 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) . . . 'To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill . . .'' *In re Robertson,* 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1991) (emphasis supplied).

Tokoro describes a method that includes injecting hens with pathogens (*i.e.,* enterotoxic *E. coli* (ETEC)) that cause intestinal infectious diseases in neonatal mammals. In response, the hens produce antibodies that are specific for the injected pathogens. The antibodies are present in eggs that are laid by the hens. The antibodies may then be used to treat the intestinal infectious diseases. Tokoro also purports that a "transfer factor-like component" may be produced by the hens in response to the injected pathogens and obtained from the eggs.

Independent claim 1, as amended and presented herein, is directed to a method for elicting a T-cell mediated immune response in an animal. The method of independent claim 1 includes, among other things, administering to the animal a composition that includes an extract of an egg obtained from a nonmammalian source animal. The extract comprises transfer factor, which is generated by way of a T-cell mediated immune response of the nonmammalian source animal to at least one antigenic agent. Further, the extract comprises a "sufficient quantity of transfer factor . . . to initiated [the] T-cell mediated immune response in the treated animal."

Independent claim 20, as amended and presented herein, recites a method for causing an animal to elicit a T-cell mediated immune response. The method of amended independent claim 20 includes "administering to the treated animal a quantity of a composition including an extract of an egg obtained from a nonmammalian source animal." The extract includes "a sufficient quantity of transfer factor . . . to initiate [a] T-cell mediated immune response in the treated animal." Additionally, the method of amended independent claim 20 includes

"permitting the transfer factor and the animal's immune system to initiate the T-cell mediated immune response *in vivo*."

It is respectfully submitted that Tokoro does not expressly or inherent describe each and every element of amended independent claim 1 or amended independent claim 20.

More specifically, it is respectfully submitted that Tokoro does not expressly or inherently describe eggs or egg extracts that include transfer factor.

First, the express description of Tokoro is limited to a "transfer factor-like component." As explained in detail in the Declaration of William J. Hennen, Ph.D., filed in U.S. Application Serial No. 09/667,147, the parent of the above-referenced application (hereinafter "the Hennen Declaration"), it is apparent from teachings in the art that "transfer factor-like" compositions are not the same as transfer factor.

Second, it is not inherent, or necessary, that transfer factor be present in the eggs of the chickens described in Tokoro, or in and products or extracts derived from those eggs. In particular, the description of Tokoro is limited to exposing chickens to antigens from ETEC. Tokoro does not disclose that the chickens are exposed to any other antigen, nor would the chickens described in Tokoro *necessarily* have been exposed to any other antigens (*e.g.*, if they were raised and maintained in a sterile environment).

Moreover, as discussed in paragraphs 16-23 of the Hennen Declaration and supported by the references cited therein, the specific ETEC antigens to which the description of Tokoro is limited may cause a nonmammalian source animal to elicit a B-cell immune response independently of a T-cell mediated immune response (*i.e.*, an immune response in which transfer factor would be generated).

Further, several references which are already of record in the above-referenced application indicate that certain pathogens, such as the ETEC mentioned in Tokoro, do not elict a secondary, or T-cell mediated, immune response and, thus, do not result in transfer factor activity. For example, Fudenberg et al., "Transfer factor 1993: new frontiers," Prog. Drug Res. 42:309-400 (1994), reports that the utility of transfer factors in bacterial conditions is notably absent. In the XI International Symposium on Transfer Factor (1999), it was reported that the use of bacterial antigens did not inherently produce any transfer factor affects: "It is worth noting that

DLE [dialyzable leukocyte extracts]obtained from two of the immunized donors lacked in vitro activity, and also failed to transfer [delayed type hypersensitivity] in vivo." Vershigora A.E., et al., "Human Specific Transfer Factor To Staphylococcus Antigens," in XIth International Congress on Transfer Factor, Universidad Autonoma de Nuevo Leon, March 1999.

Therefore, Tokoro does not inherently describe that transfer factor is present in the eggs or egg preparations or extracts that are described therein.

Even assuming, *arguendo,* that the egg preparations or extracts described in Tokoro include transfer factor, Tokoro lacks any express or inherent description that the egg preparations or extracts described therein include "a sufficient quantity of transfer factor . . . to initiate [a] T-cell mediated immune response in [a] treated animal," as required by amended independent claim 1.

While Tokoro repeatedly mentions (*see, e.g.,* col. 5, line 67, to col. 6, line 2; col. 8, line 67, to col. 9, line 6; col. 9, lines 16-19; col. 10, lines 24-30) that eggs are checked for a determination of whether the antibody titers thereof are sufficient to provide the desired response in a treated animal, Tokoro lacks any express or inherent description that the eggs or preparations made therefrom included a sufficient quantity of transfer factor to provide the desired result: a T-cell mediated immune response in a treated animal. In fact, primary and secondary immune responses occur at different times. Thus, it is clear that, in the eggs and egg preparations described in Tokoro, an optimal titer of antibody *need not* occur at the same time as a titer of transfer factor which is sufficient to initiate a T-cell mediated immune response in an animal treated with the egg or egg preparation.

Thus, Tokoro is also devoid of any express or inherent description that that any of the preparations described therein includes a sufficient quantity of transfer factor to cause the immune system of a treated animal to elicit a T-cell mediated immune response.

For these reasons, it is respectfully submitted that Tokoro does not anticipate each and every element of amended independent claim 1 or amended independent claim 20. Therefore, under 35 U.S.C. § 102(b), amended independent claims 1 and 20 recite subject matter which is allowable over that described in Tokoro.

Each of claims 2, 3, 8-16, 18, and 19 is allowable, among other reasons, for depending either directly or indirectly from claim 1, which is allowable.

Claims 21 and 22 are both allowable, among other reasons, for depending from claim 20, which is allowable.

Claim 10 is additionally allowable since Tokoro neither expressly nor inherently describes "administering to [a] treated animal [a] composition with . . . transfer factor comprising transfer factor molecules specific for at least one antigen of [a] pathogen." Instead, the description of Tokoro is limited to exposing chickens to ETEC, to which a "transfer factor-like component" is generated. Again, for the same reasons provided above with respect to amended independent claims 1 and 20, Tokoro also lacks any inherent description that the eggs obtained from the chickens and the derivative egg preparations include transfer factor.

Claim 12 is further allowable since Tokoro does not expressly or inherently describe that the eggs and egg preparations described therein include transfer factor which is "specific for at least one antigen of" ETEC.

Claim 13 is also allowable because Tokoro lacks any express or inherent description that the eggs and egg preparations described therein include transfer factor which is "specific for at least one antigen of" ETEC.

Claim 14 is additionally allowable because Tokoro neither expressly nor inherently describes that chickens may be exposed to antigens of any of Newcastle Virus, rubeola virus, mumps virus, rubella virus, Epstein-Barr Virus, hepatitis B virus, or *H. pylori*.

Claim 19 is further allowable since Tokoro includes no express or inherent description that the piglets to which the eggs and egg preparations elicited, *in vivo*, a T-cell mediated immune response.

Claim 22 is additionally allowable since Tokoro does not expressly or inherently describe that the transfer factor of the composition that is administered to the treated animal is administered in a quantity which is sufficient to "strengthen an immune system of the animal."

Allowable Subject Matter

The indication that claim 17 recites subject matter which is "free of the prior art" is gratefully acknowledged. As it is believed that claim 1, from which claim 17 depends, is also allowable, claim 17 has not yet been amended to independent form.

CONCLUSION

It is respectfully submitted that each of claims 1-22 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,

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